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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,973	08/04/2003	Vincent Sanchis	3495.0150-02	2998

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EXAMINER	
TUNG, JOYCE	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,973	SANCHIS ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/05/2004&8/4/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The applicant's preliminary amendment filed 8/4/2003 has been entered. Claims 37-48 are pending.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 37 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 45 of U.S. Patent No. 6,686,149. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 37 and 39 are drawn to a method for obtaining a nucleotide sequence that codes for the active part of a polypeptide specifically active for larvae of *S. littoralis* in which the method steps are similar with the method steps of claim 45 of U.S. Patent No. 6,686,149 except that the instant invention is use for obtaining the nucleotide sequence that codes for the active part of a polypeptide specifically active for larvae of *S. littoralis* while claim 45 of U.S. Patent

No. 6,686,149 is for obtaining the nucleotide sequence that codes for the active part of a polypeptide toxic for larvae of *S. littoralis*. Thus the instant claims 37 and 39, and claim 45 of U.S. Patent No. 6,686,149 are related as genus-species.

3. Claims 37-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-14 of U.S. Patent No. 6,942,991. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 37-39 are drawn to a method for obtaining a nucleotide sequence that codes for the active part of a polypeptide specifically active for larvae of *S. littoralis*, while claims 10-14 of U.S. Patent No. 6,942,991 are drawn to a process for obtaining a nucleotide sequence coding for a polypeptide toxic specifically toward Lepidoptera of the family Noctuidae in which the method steps cited in claim 10 are more specific than the method steps cited in claim 39 of the instant invention. Thus the instant claims 37-39, and claim 10-14 of U.S. Patent No. 6,942,991 are related as genus-species.

Specification

4. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT

(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a séparate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 37-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 37-48 are vague and indefinite because of the phrase "derived from". The phrase "derived from" is used in describing a chemical compound, which is chemically modified. It is unclear whether or not the nucleotide probe has chemical modification. Clarification is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 37-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Killer et al. (Molecular Biology of Microbial Differentiation, 1986 (Ninth Conference) pg. 217-224) in view of Honigman et al. (Gene, 1986, Vol. 42, pg. 69-77) and Suggs et al. (Proc. Natl. Acad. Sci., 1981, Vol. 78(11), pg. 6613-6617).

Killer et al. disclose cloning and expression in *E.coli* of the crystal protein gene from *B. thuringiensis* strain *aizawa* 7-29 active against *S. littoralis* (See pg. 218, column 1, forth paragraph). The restriction maps of the six cloned crystal protein genes of different *B. thuringiensis,* one of chromosomal origin (pBT15-88) and five of plasmid origin were compared after digestion by *Pvn*II, *Eco*RI, or *Hind*III and hybridization was performed with *Pvu*II fragment of pBT15-88 as a probe. *B. thuringiensis,* strain, *entomocidus* and *aiszawa* (7-29) are tested by hybridization (See pg. 219, column 2, second paragraph and pg. 220, column 1, last paragraph).

The comparison of the structural organization of the crystal protein genes of plasmid and chromosomal origins from different serotypes, six of which have been cloned in *E. coli*, revealed the existence of two classes of genes which are very similar in the restriction map corresponding to the N-terminal part of the protein and which differ essentially in the 3' region (See pg. 223, column 1, last paragraph).

Honigman et al. disclose the cloning and expression of a toxin from *B. thuringiensis*. More importantly, this reference discloses the isolation and cloning of the DNA of *B. thuringiensis* strain *entomocidus* 24. A gene coding for the delta-endotoxin on the *B. thuringiensis* plasmid is localized. The clones are isolated and detected (See pg. 69, the Abstract) by hybridization (See pg. 71, column 1, second paragraph). The study suggests that the toxin genes of various strains of *B. thuringiensis* may share common sequences and differ in their toxic activity (See pg. 76, column 1, forth paragraph).

Suggs et al. disclose use of synthetic oligonucleotides as hybridization probes: isolation of cloned cDNA sequence for human β_2-microglobulin (See pg. 6613, the Abstract).

The teachings of Killer et al., Honigman et al. and Suggs et al. suggest the limitations of claims 37-48 in which the procedure comprises hybridization, fragment isolation and cloning in a vector followed by purification, the probe is from a *aizawai* 7-29 strain, the fragment recombined with the vector is elaborated from a nucleotide sequence derived from a recombinant vector containing a sequence of *B. thuringiensis* restriction fragment HindIII-PstI derived from *aizawa* 7-29.

None of the references discloses the specificity indexes of the specifically active polypeptide as cited in claims 37, and 41-48 and the comparison of the specific toxic activity of the specifically active polypeptide with the native crystal proteins of the strains *aizawai* 7-29 or *berliner* 1715 towards *S. littaralis* as cited in claims 45-48. However, these descriptions are the

features of the active part of the polypeptide, which is coded by the nucleotide sequence. Thus these descriptions have no patentable weight.

None of the references discloses the nucleotide probe, which encodes amino acids 281-620 of the δ endotoxin of *B. thuringiensis* stain *aizawa* 7-29. However, the amino acid sequence of the δ endotoxin of *B. thuringiensis* stain *aizawa* 7-29 and the nucleic acid sequence which codes for the amino acid sequence are not presented. Thus it is not clear that what is the nucleic acid sequence for the nucleotide probe.

One of ordinary skill in the art at the time of the instant invention would have been motivated to combine the teachings of Killer et al., Hangman et al. and Suggs et al. because Killer et al. disclose cloning and expression in *E.coli* of the crystal protein gene from *B. thuringiensis* strain *aizawa* 7-29 active against *S. littoralis* (See pg. 218, column 1, forth paragraph). Killer et al. used hybridization to study the restriction maps of the six cloned crystal protein genes of various strains of *B. thuringiensis* and Honigman et al. used hybridization to detect clones. and Suggs et al. disclose using nucleic acid hybridization probe to isolate cloned cDNA sequence. Thus, it would have been prima facie obvious to carry out the method for obtaining a nucleotide sequence that codes for the active part of a polypeptide specifically active for larvae of *S. littoralis* with the steps cited in the claims.

Summary

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung
April 25, 2006

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

5/1/06